

REMARKS

The Office Action dated September 24, 2009 has been carefully reviewed and the Examiner's comments carefully considered. Claims 1-5, 7-19, and 21-29 are pending in the present application, with claims 1 and 14 being in independent form. Claims 1 and 14 have been amended. Claims 6 and 20 have been cancelled. Support for these amendments can be found in paragraphs [0030], [0044], and [0047]. Accordingly, no new matter has been added.

Claims 1, 6, 9, 10, 12-13, and 28 stand rejected under 35 U.S.C. § 103(a) for obviousness based upon non-patent literature "Hold the Lab in the Palm of Your Hand: Point-of-Care Blood Analyzers Speed Test Results at the Patient's Bedside" by McConnell (hereinafter "the McConnell publication") in view of United States Patent No. 5,897,493 to Brown (hereinafter "the Brown patent").

Claims 2-5 stand rejected under 35 U.S.C. § 103(a) for obviousness based upon the Brown patent in view of the McConnell publication and further in view of United States Patent Application Publication No. 2001/0051766 to Gazdzinski (hereinafter "the Gazdzinski publication").

Claims 7-8, 14-15, 20-24, 26-27, and 29 stand rejected under 35 U.S.C. § 103(a) for obviousness based upon the Brown patent in view of the McConnell publication and further in view of United States Patent Application Publication No. 2003/0140928 to Bui et al. (hereinafter "the Bui publication").

Summary of the Claims

Amended independent claim 1 recites, in relevant part, "receiving by a central device sample data from at least one sample testing device at a patient point of care location ... said central device adapted to maintain at least one database". Claim 1 also recites, in relevant part, "updating said database by the central device ... and providing said database to a network server". Claim 1 has been amended to recite, in relevant part, "controlling said central device to communicate new test data ...via a handheld analytical device...to sample testing device, said sample testing device updating information stored in a patient identifier label with new test data." Claim 1 also recites "tagging said received sample data with patient identifier label information".

The claimed invention allows for the creation of a “contamination zone” by enabling a hospital worker to use a sample cartridge that remains at the patient’s point of care, with the central device adapted to store sample data in a database. This aspect of the claimed invention minimizes contamination of additional testing devices, lowers the contamination risk to a healthcare professional, and is accomplished by providing the data to a central device for processing. This aspect is specifically set forth in independent claim 1 including “receiving by a central device sample data” and “updating said database by the central device ...and providing said database to a network server”. By utilizing a central device to receive and store sample data in a database, this decreases the burden to the point of care physician and device as the intense processing is removed from the point of care and located within the central device. The central device is typically a more powerful device where data can be manipulated quickly and efficiently away from contamination which enables hospitals to use cheaper streamlined devices at the point of care to perform the particular task of data collection from patients while the sample testing device is in the contamination zone. With regard to the physician, their safety burden is minimized because contact at the point of care is minimized since activities in the contamination zone are reduced. In addition, storing information in the centrally provided database enables further completion of the information record as the information arrives. Applicants respectfully submit that the Examiner’s primary cited reference, namely the Brown patent, fails to teach or suggest any of these elements.

§ 103 Rejections

The Brown patent is not directed to physician safety or contaminated devices, therefore, the teachings are not related. The Brown patent describes only a remote monitor system specifically designed for use at the patient point of care to connect to a network server. The Brown patent includes user input buttons (*see* the Brown patent, column 6, lines 46) and audio speakers (*see* the Brown patent, column 6, lines 59), particularly exemplifying that the device of the Brown patent teaches a system for working only in a contamination zone near the patient. The Brown patent further discloses a device that is to be intimately handled by a patient. Furthermore, the monitor system of the Brown patent measures the condition of a patient at the point-of-care where it will be contaminated by the patient, thus teaching away from a remote system as recited in Applicants’ claims.

Further, the monitor system of the Brown patent is combined with a second apparatus to create a remote monitor apparatus for transmitting measured information to a server (*see* the Brown patent, column 5, lines 15-19). The Brown patent specifically teaches a system that performs the entire process within the patient contamination zone. In contrast, the present invention minimizes resources spent near the point of care. The Brown patent specifically teaches away from claimed features of Applicants' invention because the data of the Brown patent is processed in the monitoring system at the point of care, and no need exists for sending sample data to a central device.

A further feature of independent claim 1 is the ability to receive sample data and to relate the data to a cartridge. Independent claim 1 recites, in relevant part, "receiving by the central device cartridge identifier information from said sample testing device". The Examiner admits the Brown patent does not disclose an analytical device connected to a sample cartridge, *i.e.*, the sample testing device in the present invention. In addition, the Examiner admits that the Brown patent does not disclose cartridge identifier information. In order to rectify these deficiencies, the Examiner has cited the McConnell publication as describing these features. However, the McConnell publication only describes a device providing barcode scanning to save time (*see* the McConnell publication, page 58, bullet 4). Accordingly, Applicants respectfully submit that this description does not obviate the need for a cartridge identifier.

With regard to the previously presented distinction between barcode scanning and tagging, Applicants respectfully submit that the Examiner has misstated the issue. The provision of barcode scanning of the McConnell publication is not equivalent to the claimed language "tagging received sample data with a patient identifier label information...[which is] communicated to said central device by a data input device" as recited in claim 1. Specifically, the patient identifier is used to correlate sample data to patient identifier label information in the database of the central device, as the presently claimed invention provides tagging "received data". Therefore the data is necessarily already on the central device when it is tagged (*see* paragraph [0043] of the present application).

In contrast, the McConnell publication describes features of a particular point-of-care monitor and lists "Laser bar-code scanning for all data entry" (*see* pages 58-59). The McConnell publication is silent as to scanning patient identifiers and certainly does not suggest a

remote system. In addition, assuming arguendo, the omitted patient identifiers are obvious, it would not be obvious for a device such as that described in the McConnell publication to send data to a central device to be tagged. One of ordinary skill in the art would understand the McConnell publication as teaching tagging of the item concurrently, using the handheld as the data is read, requiring physical presence of the operator at the point-of-care, and necessitating direct proximate access to the patient.

Applicants respectfully submit that it is inappropriate to combine the Brown patent and the McConnell publication. The Examiner states that the motivation to combine is to expedite the collection of sample analysis results utilizing a remote system at a patient point of care. However, one of ordinary skill at the time would recognize that a monitoring system serves a particular patient over a period of time. There would be no motivation to utilize the Brown patent because it was not designed for collecting sample data. Since the McConnell publication describes a docking station to which the analytical device is physically connected for downloading data, the benefit that the Examiner has stated is already offered, it cannot be a motive to combine the McConnell publication with the Brown patent for the purpose of providing an already addressed feature. Furthermore, the Brown patent and McConnell publication teach away from one another, solving the separate problem of remote monitoring and mobile testing, respectively. Their underlying priorities are contradictory, therefore, they would never be combined.

Finally, in order to expedite prosecution, Applicants have amended claim 1 to include the additional step “controlling said central device to communicate new test data as at least one data packet ... from said central device via a handheld analytical device...to sample testing device, said sample testing device updating information stored in a patient identifier label with new test data.” None of the cited references teach communicating data to a label as required by the claimed language of claim 1. In addition, none teach sending the data via a sample testing device.

The Bui publication describes a patient care system having personnel, equipment, and medication identifiers. The information included in the identifiers may be a format such as a bar code, a radio frequency (RF) device, or a readable format, such as an RFID. The Bui publication does not disclose updating information stored in a label. The Gazdzinski publication

describes using Bluetooth and other so-called "3G" (third generation) communications technologies. The Bluetooth wireless technology allows users to monitor using a single "master" device adapted to receive and store/display the streamed data received from the various patients. The Gazdzinski publication also fails to overcome this deficiency.

Accordingly, Applicants respectfully submit that none of the Brown patent, the McConnell publication, the Gazdzinski publication, or the Bui publication, alone or in any combination, teach or suggest the present invention recited in amended independent claim 1 of the present application. For the foregoing reasons, independent claim 1 is patentable over the prior art. Reconsideration of the rejection of independent claim 1 is respectfully requested.

Claims 9-10, 12-13, and 28 depend from and add further limitation to independent claim 1 and are believed to be allowable for at least the reasons stated hereinabove with regard to claim 1. Reconsideration of the rejection of claims 9-10, 12-13, and 28 is respectfully requested.

Claims 2-5 depend directly or indirectly from and add further limitations to independent claim 1. For at least the reasons stated with regard to claim 1, dependent claims 2-5 are allowable. Reconsideration of the rejection of dependent claims 2-5 is respectfully requested.

Dependent claims 7-8 depend directly or indirectly from and add further limitations to independent claim 1. For the foregoing reasons, dependent claims 7-8 are patentable. Reconsideration and withdrawal of the rejection of dependent claims 7-8 is respectfully requested.

Independent claim 14 is allowable for the reasons discussed hereinabove with regard to independent claim 1. Reconsideration and withdrawal of the rejection of independent claim 14 is respectfully requested.

Dependent claims 15, 20-24, 26-27, and 29 depend directly from independent claim 14 and are believed patentable for the reasons stated herein. Reconsideration of the rejection of dependent claims 15, 20-24, 26-27, and 29 is respectfully requested.


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CONCLUSION

Based on the foregoing amendments and remarks, reconsideration of the rejections and allowance of pending claims 1-5, 7-19, and 21-29 are respectfully requested. Should the Examiner have any questions regarding any of this information, the Examiner is invited to contact Applicants' undersigned representative by telephone at (412) 471-8815.

Respectfully submitted,

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